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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,654	07/10/2006	Tetsuya Okano	0425-1218PUS1	5662

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EXAMINER	
FISHER, ABIGAIL L	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
07/16/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/551,654	OKANO ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/05, 12/29/05, 5/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Response to USPTO Communication filed on January 28 2008 is acknowledged. Claims 5-9, 11-12, 15-21 were amended. Claims 1-21 are pending.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of the priority document has been received in this National Stage application from the International Bureau.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on September 29 2005, December 29 2005 and May 8 2006 were considered by the examiner.

Claim Interpretation

Instant claim 1 claims an organic acid having a hydrocarbon group which may have a hydroxyl group. The examiner interprets "which may have" to mean that the hydrocarbon group optionally has a hydroxyl group.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 20-21 provide for the use of the composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the sterilizing method according to claim 9" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 9 is directed to a composition. The examiner believes that this is a typo and depends from

claim 10 which is directed to a method of sterilizing. For the purposes of applying art claim 11 will be interpreted as depending from claim 10.

However, if the above interpretation of dependence is correct then claim 11 recites the limitation "the composition" in line 2. There is insufficient antecedent basis for this limitation in the claim. For the purposes of applying art "the composition" will be interpreted as being the "aqueous solution".

Claim 11 as written is vague and indefinite. It is unclear what is meant by "using". The claim does not set forth any steps involved in the method/process, and thus it is unclear what method/process they are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20-21 are rejected under 35 U.S.C. 112, second paragraph, because while the claims provide for the "use" of the composition, the claims do not set forth any steps involved in the method/process, and thus it is unclear what method/process they are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant claims a composition having a water content of 1 to 25% by weight comprising an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group which may have a hydroxyl group and hydrogen peroxide or separately claimed an inorganic peroxide releasing hydrogen peroxide.

Applicant claims a process for producing an organic peracid which comprises a step of reacting an ester of a polyhydric alcohol and an organic acid having a hydrocarbon group which may have a hydroxyl group with hydrogen peroxide in a molar ratio of 1/20 to 20/1 in water at pH 8 to 12 and then adjusting the reacting system to pH 1 to less than 7.

Claims 1-9 and 13-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Montgomery (US Patent No. 6221341, cited on PTO Form 1449).

Montgomery discloses a composition comprising glyceryl triacetate (2 %) and sodium percarbonate (5 %) and water (1.8%). The amount of glycerol triacetate corresponds to 0.009 mols and the amount of hydrogen peroxide from the sodium percarbonate corresponds to 0.005 mols. This molar amount corresponds to a ratio of glycerol triacetate and hydrogen peroxide of 9:5 which reads on the instant claimed ratio. The pH as claimed is in excess of about 5.2. As claimed the hydrogen peroxide concentration is from about 0.1 to about 15%. 0.1 % anticipates instant claim 6.

Montgomery exemplifies a composition (example IV) comprising sodium percarbonate and glyceryl triacetate in an 8:7 ratio (hydrogen peroxide: glyceryl triacetate). The composition was mixed with water, 1 part water to 5 parts gel (so a total of 20% water). This mixture quickly gave off an odor similar to acetic acid, indicating that peroxyacetic acid was forming. This composition was then placed on the surface of several teeth for 60 minutes.

Regarding the claimed pH, Montgomery discloses that the pH is in an excess of 5.2. Montgomery is silent as to the adjustment of the pH. However, it is the examiner's position that as the peroxyacetic acid is generated the pH of the solution would necessarily reduce. Since the components of Montgomery's composition are the same as instantly claimed it is the examiner's position that the adjustment in pH would be the same as instantly claimed. It is incumbent on applicant to demonstrate that the pH change would not be the same.

Claims 1-9, 13-18 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Speed et al. (US Patent No. 6399564).

Speed et al. are directed to detergent tablets. Examples A and B disclose compositions that comprises PB1, which is sodium perborate (12.6 or 12.5 g), glycerol triacetate (34 g), and water (23.5 g). This correlates to a molar ratio of glycerol triacetate to hydrogen peroxide of 4/1 and a water percentage of 11%. It is taught that the tablets comprise two portions a compressed portion and a non-compressed portion. Regarding the pH of the composition, the compressed portion is formulated to deliver

an alkaline pH (from 8 to 12.5) while the non-compressed portion is formulated to deliver an acidic pH of less than 7 (column 48, lines 61-67). It is taught that the non-compressed portion can have a delayed dissolution (column 10, liens 11-12). Therefore, the pH of a solution would initially have the pH of the compressed portion and then once the non-compressed portion begins to dissolve the pH will adjust to a lower pH. The amount of inorganic perhydrate salts that can be incorporated from 1 to 40% which corresponds to a hydrogen peroxide content of about 0.34% to about 14% (column 11, lines 54-57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montgomery in view of Karlson (US Patent No. 4517159).

Applicant Claims

Applicant claims a method of sterilizing a material which comprises contacting with the material an aqueous solution containing an organic peracid obtained by reacting an ester of polyhydric alcohol and an organic acid having a hydrocarbon group which may have a hydroxyl group with hydrogen peroxide in a molar ratio of 1/10 to 20/1 in water at pH 8 to 12 and then adjusting the reacting system to pH 1 to less than 7

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Montgomery are set forth above. Specifically, Montgomery teaches a formulation comprising a hydrogen peroxide source, glyceryl triacetate. It is disclosed that the pH is in excess of 5.2. It is taught that this pH is optimal for the formation of the peroxyacetic acid that forms from hydrogen peroxide and glyceryl triacetate (column 8, lines 14-16).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Montgomery does not specify that the compositions can be utilized in a method of sterilizing. Montgomery does not specify that the pH starts at value from 8 to 12 and then is adjusted to a pH of 1 to less than 7. However, these deficiencies are cured by Karlson.

Karlson is directed to a sterilizer. It is taught that hydrogen peroxide is a known water soluble sterilizing agent (column 3, lines 17-20).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Montgomery and Karlson and utilize the composition of Montgomery as a sterilizer. One of ordinary skill in the art would have been motivated to utilize the composition as a sterilizer because it contains hydrogen peroxide which is a known sterilizing agent. Therefore, one of ordinary skill in the art would have had a reasonable expectation that the composition could be utilized in a method of sterilizing.

Regarding the adjustment of pH, Montgomery is silent as to the change in pH. However, it is taught that as hydrogen peroxide reacts with glyceryl triacetate that peroxyacetic acid is formed. As this acid is generated the pH would necessary lower. Since the active ingredients of Montgomery are the same as instant claimed it is the examiner's position that the relative change in pH would be the same as instant claimed. Therefore, it is incumbent on applicant to demonstrate that the formation of peroxyacetic acid would not result in the pH adjustment as instantly claimed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speed et al. in view of Karlson.

Applicant Claims

Applicant claims a method of sterilizing a material which comprises contacting with the material an aqueous solution containing an organic peracid obtained by reacting an ester of polyhydric alcohol and an organic acid having a hydrocarbon group which may have a hydroxyl group with hydrogen peroxide in a molar ratio of 1/10 to 20/1 in water at pH 8 to 12 and then adjusting the reacting system to pH 1 to less than 7

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The teachings of Speed et al. are set forth above. Speed et al. teach compositions comprising a hydrogen peroxide source, glycerol triacetate, and water.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Speed et al. does not specify that the compositions can be utilized in a method of sterilizing. However, these deficiencies are cured by Karlson.

Karlson is directed to a sterilizer. It is taught that hydrogen peroxide is a known water soluble sterilizing agent (column 3, lines 17-20).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Speed et al. and Karlson and utilize the composition of Speed et al. as a sterilizer. One of ordinary skill in the art would have been motivated to utilize the composition as a sterilizer because it contains hydrogen peroxide which is a known sterilizing agent. Therefore, one of ordinary skill in the art would have had a reasonable expectation that the composition could be utilized in a method of sterilizing.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616